

**Notice of Allowability**

Application No.

10/812,831

Examiner

Andrew D. Kosar

Applicant(s)

PASHA ET AL.

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/30/07.
2. ☒ The allowed claim(s) is/are 1, 7-9, 18-23 and 28.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 5. <input type="checkbox"/> Notice of Informal Patent Application  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>20070913</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                         |
|  | 9. <input type="checkbox"/> Other _____  |

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative, Clifford Mass, on September 13, 2007.

### *Response to Amendments/Arguments*

Applicant's amendments and arguments filed August 30, 2007 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn. In accordance with Markush practice, the search was extended to the additional species recited in the claims. The species were found to be allowable in view of the prior art.

In view of the examiner's amendment below, claims 1, 7-9, 18-23 and 28 are allowed:

### *Election/Restrictions*

Claim 1 is directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 9 and 18-21, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on November 1, 2005 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a

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continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

***Examiner's Amendment***

The application has been amended as follows:

In the claims listing of August 30, 2007:

**REPLACE claim 1** with the following:

A peptidomimetic compound having the general formula Xaa-AA<sub>1</sub>-AA<sub>2</sub>, where

Xaa is a heterocyclic or unusual amino acid;

AA<sub>1</sub> and AA<sub>2</sub> are amino acids; and

the bond between Xaa and AA<sub>1</sub> is either C(O)-NH or CH<sub>2</sub>-NH,

wherein AA<sub>1</sub> is Ornithine, AA<sub>2</sub> is Proline and Xaa is L-Abrine.

**REPLACE claim 7** with the following:

A composition comprising the peptidomimetic compound according to claim 1, wherein the composition comprises a concentration of the peptidomimetic compound for 50% inhibition (IC<sub>50</sub>) of angiotensin converting enzyme (ACE) activity.

**REPLACE claim 9** with the following:

A process to synthesize the peptidomimetic compound of claim 1, comprising:

(a) synthesizing the dipeptide AA<sub>1</sub>-AA<sub>2</sub> on a solid support;

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(b) coupling the heterocyclic or unusual amino acid to the N- $\alpha$  terminal of the dipeptide;  
(c) cleaving the synthesized peptidomimetic compound from the solid support; and  
(d) purifying the peptidomimetic compound; thereby forming the peptidomimetic of claim 1.

**REPLACE claim 18** with the following:

A method for inhibiting an angiotensin converting enzyme in a mammal comprising administering the peptidomimetic compound of claim 1 to the mammal.

**REPLACE claim 20, line 1** with the following:

A method of inhibiting angiotensin converting enzyme in a subject

**REPLACE claim 21** with the following:

The method according to claim 20 wherein the subject is a mammal.

**REPLACE claim 22** with the following:

The method according to claim 22 wherein the subject is a human.

**REPLACE claim 23, line 1** with the following:

The method according to claim 20 wherein the peptidomimetic compound is

**REPLACE claim 28, line 2** with the following:

peptidomimetic compound having the formula Xaa-AA<sub>1</sub>-AA<sub>2</sub>, wherein Xaa is a

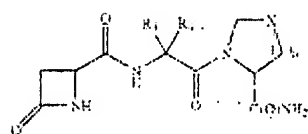
**REPLACE claim 28, line 5** with the following:

from the group consisting of L-Abrine-Orn-Pro, 3-(3-thienyl)-L-alanine-Orn-Pro, 3-(2-

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The following is an examiner's statement of reasons for allowance:

The closest prior art, RIVIER (J. Med. Chem. (1972) 15(5), pages 479-482) and KOZIKOWSKI (US Patent 7,202,279 B1), do not teach or suggest, alone or in combination with any other art of record, the instantly claimed compounds or the methods of making or using. Rivier teaches tripeptides having the structure pGlu-AA<sub>1</sub>-ProNH<sub>2</sub>, including pGlu-Orn-ProNH<sub>2</sub>, as thyrotropin-releasing factor (TRF) analogs; however there is no teaching or suggesting, alone or in combination with any other art of record, to substitute pGlu to any of the instantly claimed Xaa. Kozikowski teaches Azetidinone compounds having the general structure



, as TRF analogs, however there is no teaching or suggestion, alone or in combination with any other art of record, to replace the azetidinone with azetidine or any other Xaa instantly claimed and to use the Xaa-Orn-Pro as the core structure.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Claims 1, 7-9, 18-23 and 28 are allowed in view of the examiners amendment, above.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913.

The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew D Kosar  
Patent Examiner, Art Unit 1654